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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,656	08/08/2001	Denis Schrier	5660-D1-01-CFP	5347

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EXAMINER	
DEEMIE, ROBERT W	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,656	SCHRIER ET AL.	
	Examiner	Art Unit	#4
	Robert W. Deemie	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☒ Claim(s) 1 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/403,867* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. No new matter should be added.

The following title is suggested: Anti-Inflammatory Method Using Gamma-Aminobutyric Acid (GABA) Analogs.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of inflammation, does not reasonably provide enablement for prevention of inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The metes and bounds of prevention encompass all causes of inflammatory diseases, including physical trauma. A GABA analog will not prevent physical trauma, nor can an applicant assert with credibility that a single genus of organic compounds can prevent all manifestations of inflammatory diseases. The scope of the claimed invention for prevention of inflammatory diseases by using chemical compounds is too broad.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saltzinger et al. (U.S. 4,024,175), and further in view of Nagai (JP 60036413).

Determining the scope and contents of the prior art.

8. The invention is a method of preventing and treating inflammatory diseases using anti-inflammatory amount of GABA analogs.

Saltzinger teaches (col. 2:27-30) that GABA analogs containing a cyclic alkyl 5-7 membered ring substituent on the delta (# 3) carbon atom of GABA can be used to treat cranial trauma. Nagai teaches that GABA itself treats inflammatory diseases (abstract Advantage paragraph, line 3).

Ascertaining the differences between the prior art and the claims at issue.

9. Saltzinger does not expressly teach that GABA analogs have a general utility to treat inflammatory diseases. Nagai does not teach that GABA analogs can treat inflammatory diseases.

Resolving the level of ordinary skill in the pertinent art.

10. The person possessing ordinary skill in this art would be a team of medical researchers, including biologists, medicinal chemists, biochemists, or physicians, conversant in using standard drug-discovery protocols. Knowledge of drugs assays and structure activity relationships is required. The breadth and depth of expertise needed is normally considered to be at the B.S. to Ph.D./M.D. levels.

Considering objective evidence present in the application indicating obviousness or nonobviousness.

Saltzinger and Nagai are analogous because they are from the same field of endeavor, namely treating inflammatory diseases using either GABA or GABA analogs. One of ordinary skill in the art at the time of invention would have had an expectation of success due to the teachings

that both GABA and analogs of GABA have utility in treating inflammatory diseases. The suggestion / motivation for doing so would have been because cerebral trauma is a medical condition caused by swelling. Swelling is an inflammatory process. Saltzinger teaches (col. 2:27-30) that GABA analogs can treat cerebral trauma. Therefore, it would have been obvious to use GABA analogs as taught by Saltzinger to treat inflammatory diseases as taught by Nagai to obtain the invention as specified in claim 1 of the instant invention.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,329,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application embraces the entirety of claim 1 in U.S. Patent No. 6,329,429.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Deemie whose telephone number is (703) 305-5734. The examiner can normally be reached on M-F (9:00 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary examiner, Sreenivasan Padmanabhan, the Primary Examiner signing this action, can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Robert W. Deemie
Examiner
Art Unit 1623

Sreenivasan Padmanabhan
Primary Patent Examiner
Art Unit 1621

6/28/02

RWD
Friday, June 28, 2002